K080129

MAY 30 2008

510(K) SUMMARY

Secure Implant System (2.5/3.0mm)

14-1. Submitter	DSI Jin Choel, Kim(President) Eun Jin, Kim(Regulatory affair staff) 117 Kyo-Dong, Yangsan-City Kyungnam-Do, 626-210, Korea Phone: 82-55-383-7900 Fax : 82-55-363-3404
14-2. US Agent / Contact Person	Hyungick Kim/ Timothy Lee 3540 Wilshire Blvd. #1104 Los Angeles, CA 90010, USA Phone : 213-365-2875, Fax : 213-365-1595
14-3. Date Prepared	January 08, 2008
14-4. Device Name	SECURE IMPLANT SYSTEM(2.5/3.0MM)
14-5. Classification Name	Endosseous Dental Implant System
14-6. Device Classification	Class II Dental Devices panel Regulation Number: 21 CFR ξ 872.3640
14-7. Predicate Devices	INTERMEZZO ™ Plus(510(k) No.: K053354) Zimmer One-Piece Implant System (510(k) No.:K052997)
14-8. Performance	Laboratory testing was conducted to determine device functionality and conformance to design input requirements.

14-9. Device Description

Secure Implant System(2.5/3.0mm) is a root-form threaded dental implant made of titanium alloy. The implant is produced by machining process, followed by grit blasting and cleaning. It is available in diameters 2.5 and 3.0mm, and lengths from 8mm to 16mm.

14-10. Packing / Labeling / Product Information

In a clean room that is Class 10,000 or less, put the product into a plastic ampoule, and then put the plastic ampoule in a pet container, then sealed the pet container with Tyvek®. Secure Implant System(2.5/3.0mm) will be packaged.

14-11. Intended Use

Secure Implant System(2.5/3.0mm) is designed for use in dental implant surgery and is intended for use in a manner in which the implants integrate with the bone(osseointegration). It is intended to provide immediate transitional splinting stability or intrabony long-term fixation of new or existing crown, bridge and denture installations in partially or fully edentulous patients

14-12. Substantial Equivalence Comparison

TECHNOLOGICAL CHARACTERISTIC COMPARISON

	Subject Device	**Predicate Device II**
Manufacturer Name	DSI	Mega'Gen Co., Ltd.
Device Name	Secure Implant System (2.5/3.0mm)	Intermezzo ™ Plus (K053354)
Intended Use	Secure Implant System(2.5/3.0mm) is designed for use in dental implant surgery and is intended for use in a manner in which the implants integrate with the bone(osseointegration). It is intended to provide immediate transitional splinting stability or intrabony long-term fixation of new or existing crown, bridge and denture installations in partially or fully edentulous patients	Intermezzo ™ Plus are gned for use in dental implant surgery and are intended to be used in a manner in which the implants integrate with the bone (osseointegration). The system is intended for use in partially or fully edentulous mandibles and maxillae, in support of overdentures.
Material	Titanium Alloy	CP-Ti Gr3
Screw Threads	YES	YES
Implant Thread Diameter(mm)	2.5/3.0	2.5-3.1
Lengths(mm)	8.0-16.0	10.0-15.0
Surface Treatment	Yes	No
Sterilized	GAMMA	GAMMA

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR & 807.93

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 30 2008

DIO Department, DSI, Incorporated
C/O Mr. Hyungick Kim
Manager
DIO, USA
3540 Wilshire Boulevard, Suite 1104
Los Angeles, California 90010

Re: K080129
Trade/Device Name: Secure Implant System (2.5/3.0mm)
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: May 8, 2008
Received: May 12, 2008

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080129

Indication for Use

510(K) Number (if known): _____

Device Name: Secure Implant System (2.5/3.0mm)

Indications For Use:

Secure Implant System(2.5/3.0mm) is designed for use in dental implant surgery and is intended for use in a manner in which the implants integrate with the bone(osseointegration). It is intended to provide immediate transitional splinting stability or intrabony long-term fixation of new or existing crown, bridge and denture installations in partially or fully edentulous patients

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080129

Prescription Use _____X_____ AND/OR _____ Over – The-Counter Use
(Part 21 CFR 801 Subpart D) (Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)